

0137 '00 DEC -7 P1:47

November 27, 2000

Janet Woodcock, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

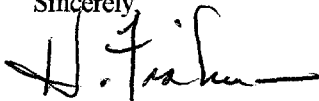
Dear Dr. Woodcock:

My name is Harold Fishman. I am a Board-Certified Gastroenterologist and Practicing Partner with Digestive Specialists in Dayton, Ohio. I obtained my medical degree from Thomas Jefferson Medical College, Philadelphia, PA in 1951. I completed my Internship at the Albert Einstein Medical Center in Philadelphia, PA. Subsequently, I concluded my Residency Program both at the Albert Einstein Medical Center in 1952-53 and the Veterans Administration Center in Dayton, Ohio in 1960-62. My Fellowship in Gastroenterology was completed in 1964 at the Veterans Administration Center in Dayton, Ohio.

The purpose in composing this letter is to express my concern over the adverse publicity the drug alosetron (Lotronex) has received in the press. Until alosetron was made available there was no pharmacological agent indicated for the treatment of diarrhea-predominant IBS. In fact, the entire marketplace was devoid of drugs that would effectively treat this condition. If Lotronex is removed from the marketplace it would mean repudiating the many benefits my, as well as my counterparts and peers, patients have experienced. It has been my experience that Lotronex remains the most effective choice of usable drugs to treat diarrhea-predominant IBS. In the many patients that I am currently treating with Lotronex I have yet to ascertain patients experiencing ischemic colitis. In fact, ischemic colitis can and does occur in the general patient population, those patients not taking Lotronex with an incidence similar to what was reported in clinical trials with Lotronex. With appropriate patient usage and education, Lotronex will continue to be the most effective and safe choice for the treatment of diarrhea-predominant IBS.

I've read the various negative accounts that have been reported in the news. In light of the erroneous reports of ischemic colitis being associated to Lotronex I have yet to see a causal relationship between the two. With the exception of constipation, which does occur with Lotronex and can be treated with supportive measures, the side effect profile has been well tolerated. In my view, there still remains enough doubt as to what causes ischemic colitis; and certainly the improvement in my patients quality of life while on Lotronex therapy warrant it's remaining viable in the marketplace.

Sincerely



Harold Fishman M.D.
Gastroenterologist, Digestive Specialists

00P-1499

C50



HAPPY
HOLIDAYS
from the
U.S. Postal Service



**Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services, Room 1 - 23
12420 Parklawn Drive
Rockville, Maryland 20857**

